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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/038,686	01/04/2002	Tihamer Orban	10276-067001/JDP 067	4856

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EXAMINER	
EWOLDT, GERALD R	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 02/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/038,686	ORBAN, TIHAMER	
	Examiner	Art Unit	
	G. R. Ewoldt, Ph.D.	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 November 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) *1-9,11,12,15,20 and 25-30* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10,13,14,16-19 and 21-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's election without traverse of Group II, Claims 10-24, and the autoantigen species: insulin B-chain, filed 11/22/04, is acknowledged.

2. Claims 1-9 and 25-30 are withdrawn from further consideration by the Examiner, under 37 C.F.R. § 1.142(b) as being drawn to nonelected inventions. Claims 11, 12, 15, and 20 are withdrawn from further consideration by the Examiner, under 37 C.F.R. § 1.142(b) as being drawn to nonelected species.

Claims 10, 13, 14, 16-19, and 21-24 are being acted upon.

3. The declaration is objected to because the citizenship of the Inventor is not disclosed. A new declaration is required.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 13 and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, specifically:

A) Claim 13 depends on non-elected Claim 12.

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States

7. Claims 10, 13, 16, and 17 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Ramiya et al. (1996, IDS).

Ramiya et al. teaches a pharmaceutical composition comprising a type 1 diabetes autoantigen, specifically, a synthetic human insulin B-chain fragment comprising amino acids 33-37 of SEQ ID NO:1 (SHLVE) in the oil-based adjuvant IFA (see particularly page 350, column 1, *Subcutaneous immunizations of NOD mice* and peptide p(1-15)).

The reference clearly anticipates the claimed invention.

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ramiya et al. (1996, IDS) in view of U.S. Patent No. 6,462,185.

Ramiya et al. has bee discussed above.

The reference teaching differs from the claimed invention only in that it does not teach solubilizing the insulin B-chain peptide in urea.

The '185 patent teaches that urea buffers are routinely used to solubilize essentially insoluble proteins (see particularly column 21, lines 61-63).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to solubilize the insulin B-chain peptide of Ramiya et al. in the urea buffer of the '185 patent. One of ordinary skill in the art would have been motivated to employ a urea buffer given the teaching of the '185 patent that urea buffers can be used to solubilize even essentially insoluble proteins.

10. Claims 19, 21, 23, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ramiya et al. (1996, IDS) in view of U.S. Patent No. 4,281,061.

Ramiya et al. has been discussed above.

The reference teaching differs from the claimed invention only in that it does not teach the peptide of the claims in kit form.

The '061 patent teaches that reagents can be provided in kits as a matter of convenience and for the optimization of their use (see particularly column 22, line 62 - column 23, line 4).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to provide the insulin B-chain peptide of Ramiya et al. in the kit form of the '061 patent. One of ordinary skill in the art would have been motivated to provide said kit given the teachings of the '061 patent that reagents can be provided in kits as a matter of convenience and for the optimization of their use. Note that the kit of the '061 patent does not include instructions. MPEP 706.03(a) makes it clear that printed matter, which would include instructions, does not add patentable weight to a product because printed matter does not comprise a statutory class of invention. See also MPEP 2111.03 wherein it states that, while intended use recitations and other types of functional language cannot be entirely disregarded, in apparatus, article, and composition claims, intended use must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the limitations of the claims. Such is the case with the invention of the instant claims.

11. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ramiya et al. (1996, IDS) in view of U.S. Patent No. 4,281,061, as applied to Claims 19, 21, 23, and 24 above, in further view of U.S. Patent No. 5,447,843.

Ramiya et al. and the '061 patent have been discussed above.

The combined reference teachings differ from the claimed invention only in that they do not teach a lyophilized insulin B-chain peptide autoantigen.

The '843 patent teaches that proteins in kits can be lyophilized for convenience (see particularly column 10, lines 24-35).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to provide the insulin B-chain peptide in lyophilized form, as taught by the '843 patent, in the kit of the combined Ramiya et al. and '061 patent references. One of ordinary skill in the art would have been motivated to provide said lyophilized insulin B-chain peptide given the teachings of the '843 patent that proteins in kits can be lyophilized for convenience.

12. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

13. Claims 13, 18, 19, and 21-24 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

Under *Vas-Cath, Inc. v. Mahurkar* , 19 USPQ2d 1111, 1117 (Fed. Cir. 1991), to satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in *possession* of the invention, and that the invention, in that context, is whatever is now claimed.

There is insufficient written description to show that Applicant was in possession of "an immunologically active fragment of a variant" of the autoantigen of the instant claims.

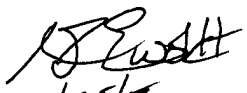
The specification discloses no such fragment or variants. The specification does disclose that variants can include sequence and non-sequence modifications. Non-sequence modifications include acetylations, methylations, phosphorylations, carboxylations, and glycosylations. Sequence modifications include naturally occurring and non-naturally occurring amino acids, as well as substitutions, deletions and insertions, both conservative and non-conservative. It is clear then that the claims encompass an essentially unlimited genus of peptides, none of which are disclosed. While the specification, at pages 32-36, may disclose how to make the claimed fragments and variants, said disclosure is not an actual description of the products made. Accordingly, one of skill in the art would conclude that the specification fails to disclose a representative number of species to describe the claimed genus of peptides. See *Eli Lilly*, 119 F.3d 1559, 43 USPQ2d 1398.

14. No claim is allowed.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (571)272-0843. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30

pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.

16. **Please Note**: Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



1/25/08

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